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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/982,299	10/16/2001	Timothy R. Ryan	M190.137.101	7830

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EXAMINER

MATTHEWS, WILLIAM H

ART UNIT PAPER NUMBER

3738

DATE MAILED: 08/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/982,299

Applicant(s)

RYAN ET AL.

Examiner

William H. Matthews (Howie)

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16,30,33 and 37-45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16,30,33 and 37-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION***Response to Arguments***

Applicant's arguments with respect to claims 1-4, 7, 9-16, 30, 33, 37-45 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

1. Claims 1-9, 44, and 45 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Independent claims 1, 44, and 45 each contain new limitations that are not supported in the specification or shown in the drawings.

With regard to claim 1, "an arc length of the stiffening element is not less than one-half the perimeter length of the sheath" is not described. Note this limitation implies Applicant's invention may include a stiffening element that is only one half the sheath element.

With regard to claim 44, "a perimeter shape of the sheath is defined by the stiffening element for at least one-half a perimeter length of the sheath". Note this limitation implies Applicant's invention may include a stiffening element that defines only one half the sheath shape.

With regard to claim 45, the use of the term "intermediate section" is inconsistent with the definition of "intermediate section" used in the specification.

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Additionally the first and second points and the linear distance, as used in claim 45, are therefore not described in the specification.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this

Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-4,7,9-13,15,16, and 37-43 are rejected under 35 U.S.C. 102(b) as being anticipated by Wright et al. US PN 5,306,296.

Wright et al. discloses in figures 2 and line 48 of col. 13 through line 66 of col. 14 annuloplasty devices comprising a fabric sheath and radiopaque arcuate stiffening wire 35 entirely disposed within the sheath having a thickness less than about 3.0 mm and ends bent back on itself to form eyelets. Markers 38 are located at the eyelets. With specific regard to claim 1, a sheath perimeter length may be defined in figure 2 as slightly larger than an arc length of the stiffening element. Figure 4B shows a stiffening element configured to independently maintain a generally saddle shape in a Z-plane and arcuate in X and Y planes. Furthermore, claims 2-3 recite intended use limitations, which do not structurally limit the invention.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 5, 6, and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wright et al. US PN 5,306,296 as applied to claims 1,4,7 in the 102(b) rejection above, and further in view of Carpentier et al. US PN 5,061,277.

Wright et al. discloses an annuloplasty device meeting the structural limitations of claims 5, 6, and 8 as described above, but lacks the express disclosure of the stiffening element having the three particular radii of curvature and a silicon overmold. Carpentier et al. teaches in figures 1 and 3, lines 9-16 of col. 3, and line 57 of col. 3 through line 7 of col. 4 an annuloplasty device having a sheath and stiffening ring wherein the stiffening ring has the three particular radii of curvature (of claim 8) to properly fit the shape of the natural mitral valve, and furthermore adds a silicone overmold to make the band soft and compressible as well as more resilient.

Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the annuloplasty sheath and stiffening element disclosed by Wright et al. by using the particular shape and overmold

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taught by Carpentier et al. in order to properly fit the shape of the natural mitral valve and make the band soft and compressible as well as more resilient.

5. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wright et al. US PN 5,306,296 as applied to claim 1 in the 102(b) rejection above, and further in view of Loch et al. US PN 6,174,332.

Wright et al. discloses an annuloplasty device meeting the structural limitations of claim 14 as described above, but lacks the express disclosure of the sheath being formed of biological tissue. Loch et al. teaches in lines 44-57 of col. 3 an annuloplasty ring having a sheath made of biological tissue to provide sufficient biocompatibility.

Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the annuloplasty sheath disclosed by Wright et al. by using biological tissue as taught by Loch et al. in order to provide sufficient biocompatibility.

6. Claims 30,33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wright et al. US PN 5,306,296 as applied to claim 1 in the 102(b) rejection above, and further in view of Howanec, Jr. et al. US PN 6,183,512.

Wright et al. discloses an annuloplasty device meeting the structural limitations of claims 30 and 33 as described above, but lacks the express disclosure of the band thickness being no greater than 2.5 mm. Howanec, Jr. et al. teaches in lines 64 of col. 2 through line 11 of col. 3 and lines 60-65 of col. 4

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an annuloplasty ring having an overall diameter less than 2.5 mm in order to maintain flexibility yet permit suturing to the annulus.

Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the annuloplasty band disclosed by Wright et al. by using an annuloplasty ring having an overall diameter less than 2.5 mm, as taught by Howanec Jr. et al. in order to maintain flexibility yet permit suturing to the annulus.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Matthews (Howie) whose telephone number is 703-305-0316. The examiner can normally be reached on Monday-Friday 10-6:30PM.

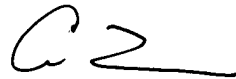
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M. McDermott can be reached on 703-308-2111. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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